.09/047,652

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FIRST NAMED APPLICANT ATTY, DOCKET NO APPLICATION NUMBER FILING DATE 09/047,652 03/25/98 **PAPADOPOULOS** HM12/0513 PAPER NUMBER PRATT & ASSOCIATES 10821 HILLBROOKE LANE 0 POTOMAC MD 20854 DATE MAILED: 05/13/99 This is a communication from the examiner in charge of your application. COMMISSIONER OF PATENTS AND TRADEMARKS **OFFICE ACTION SUMMARY** Responsive to communication(s) filed on This action is FINAL. Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 D.C. 11, 453 O.G. 213. A shortened statutory period for response to this action is set to expire whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will eaust the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a). **Disposition of Claims** is/are pending in the application. Of the above, claim(s) is/are withdrawn from consideration. Claim(s)_ is/are allowed. is/are rejected. Claim(s)_ Claim(s) _ is/are objected to. Claim(s) _ are subject to restriction or election requirement. **Application Papers** See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948. The drawing(s) filed on ___ _____is/are objected to by the Examiner. The proposed drawing correction, filed on is approved disapproved. The specification is objected to by the Examiner. The oath or declaration is objected to by the Examiner. Priority under 35 U.S.C. § 119 Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d). ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received. received in Application No. (Series Code/Serial Number) received in this national stage application from the International Bureau (PCT Rule 17.2(a)). *Certified copies not received: Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e). Attachment(s) Notice of Reference Cited, PTO-892 Information Disclosure Statement(s), PTO-1449, Paper No(s). Interview Summary, PTO-413 ■ Notice of Draftperson's Patent Drawing Review, PTO-948 Notice of Informal Patent Application, PTO-152 -SEE OFFICE ACTION ON THE FOLLOWING PAGES--

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Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-2, drawn to a composition comprising a ribozyme capable of digesting PBR RNA, classified in class 536, subclass 24.5. Claim 1 is examined with Group I to the extent that it reads on a ribozyme capable of digesting PBR RNA.
- II. Claims 1, 3, 15, 20, 32-34, drawn to polynucleotides encoding PBR and complements, compositions, vectors and host cells comprising said polynucleotides, classified, for example, in class 536, subclass 23.1. Claims 1 and 20 are examined with Group II to the extent they read on polynucleotides encoding PBR and complements.
- III. Claims 1, 4, 20, drawn to an antagonist of PBR, classified in class 530, subclass 300. Claims 1 and 20 are examined with Group III to the extent that they read on antagonists of PBR.
- IV. Claims 5-7, drawn to a method of inhibiting cell proliferation comprising the administration of an anti-sense polynucleotide, classified in class 514, subclass 44.
- V. Claims 8-11, drawn to a method of diagnosis comprising contacting a sample with an anti-PBR antibody, classified in class 435, subclass 7.1.
- VI. Claims 12-13, 20, 27, drawn to antibodies to PBR, classified in class 530, subclass 387.1. Claims 20 and 27 are examined with Group VI to the extent that they read on antibodies to PBR.
- VII. Claims 14, 30-31, drawn to a method of diagnosis comprising hybridization to polynucleotides encoding PBR, classified in class 435, subclass 6.
- VIII. Claims 16-19, drawn to a treatment method comprising the administration of a ribozyme, classified in class 514, subclass 44. Claims 16-18 are examined with Group VIII to the extent that they read on the administration of a ribozyme
- IX. Claim 21, drawn to treatment method comprising the administration of a PBR protein, classified in class 514, subclass 2.

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X. Claims 16 and 22, drawn to a treatment method comprising the administration of a polynucleotide, classified in class 514, subclass 44. Claim 16 is examined with Group X to the extent that it reads on the administration of a polynucleotide.

- XI. Claims 16 and 23, drawn to a treatment method comprising the administration of a PBR ligand, classified in class 514, subclass 2. Claim 16 will be examined with Group XI to the extent that it reads on the administration of a PBR ligand.
- XII. Claims 24-26, drawn to an *in vitro* method for testing possible agents comprising measuring ability of said agent to decrease PBR activity in an *in vitro* assay, classified in class 435, subclass 4.
- XIII. Claims 27-29, drawn to a PBR ligand, classified in class 530, subclass 350. Claim 27 is examined with Group XIII to the extent that it reads on a PBR ligand.
- XIV. Claims 35-26, drawn to a PBR negative cell, classified in class 435, subclass 325.
- The inventions are distinct, each from the other because of the following reasons:
 Inventions of Groups I-III, VI, XIII and XIV are structurally and functionally different products which are made by different methods and have different uses. The examination of all groups would require different searches in the U.S. Patent Shoes and the scientific literature and would require the consideration of different patentability issues.

The methods of Groups IV-V, VII-XII differ in the method objectives, method steps and parameters and in the reagents used.

Inventions I and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the ribozyme of Group I can also be used in methods of diagnosis.

Inventions II and each of IX, VII and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotide of Group II can be used in each of the different methods of Groups IV, VII and X.

Inventions VI and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product

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as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group VI can also be used in *in vivo* treatment methods.

Inventions XIII and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the ligand of Group XIII can also be used in methods of in *in vitro* diagnostic methods.

- 3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter and because the searches required for the groups are not co-extensive, restriction for examination purposes as indicated is proper.
- 4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).
- 5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy Johnson whose telephone number is (703) 305-5860.

Nancy A Johnson Primary Examiner

May 5, 1999